



MONTANA STATE PRISON HEALTH SERVICES OPERATIONAL PROCEDURE

Procedure No.: MSP HS B-01.3	Subject: RAPID HIV & HEP C TESTING
Reference: NCCHC Standard P-B-01,2014; HS E-12.0 Continuity of Care During Incarceration	Page 1 of 3 and 4 attachments
Effective Date: November 1, 2010	Revised: June 1, 2017
Signature / Title: /s/ Cindy Hiner / Health Services Manager	
Signature / Title: /s/ Tristan Kohut, D.O./ Medical Director	

I. PURPOSE

To conduct routine diagnostic HIV & Hep C testing of all inmates in conjunction with educational programs for risk reduction as well as for effective HIV & Hep C care at MSP and in the community after release.

II. DEFINITIONS

- a. HIV - stands for human immunodeficiency virus
- b. Hep C - is a liver infection caused by the Hepatitis C virus (HCV)

III. PROCEDURE

A. General Requirements

1. The Rapid HIV 1/2 Antibody Test is used to detect antibodies to the human immunodeficiency virus (HIV-1 and HIV-2) with oral fluid, plasma, fingerstick and/or venipuncture whole blood specimens. This test allows individuals to know their HIV status as quickly as 20 minutes.
2. The Rapid HCV Antibody Test is used to detect HCV antibodies in fingerstick and venipuncture whole blood. This test allows individuals to know their Hep C status as quickly as 20 minutes.
3. General Testing Requirements of the Facility is as follows:
 - a. the facility conducting testing must have a clinical laboratory that holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate);
 - b. the facility conducting testing must have an established quality improvement program;
 - c. the facility conducting testing must provide training for testing personnel using the instructional materials provided by the manufacturer;
 - d. the facility conducting HIV testing must provide information to persons being tested by giving each a copy of the manufacture's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results;
 - e. medical staff conducting testing must be properly trained by an approved using the *Training Checklist for OraQuick Rapid HIV & Hep C Testing (attachment A)*. This training will be tracked and training records maintained by the Nurse Educator RN;
 - f. all staff involved in testing will follow the written step-by-step instructions for oral testing utilizing *recommended steps by OraQuick Quick Reference Guides (see <https://orc.orasure.com>)* and
 - g. the testing will not be utilized to screen for blood and tissue donors.
4. HIV & Hep C screening at MSP is as follows:
 - a. screening is conducted as part of the intake process, and every inmate will be offered HIV & Hep C testing;
 - b. risk factors (e.g., IV drug use, multiple sex partners) will be determined as part of the intake assessment and H & P; and

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- c. all inmates will be strongly encouraged to participate in the HIV & Hep C testing.
5. HIV testing at MSP consists of the following:
 - a. general consent for medical care is sufficient for HIV & Hep C testing. A separate, written consent for an HIV & Hep C test will not be required;
 - b. testing is “opt-out testing,” and in the event of a refusal the inmate is not required to submit a refusal form;
 - c. no inmate will be tested without prior knowledge that the test will be conducted;
 - d. oral testing for HIV and finger stick for Hep C will be the testing method of choice unless contraindicated;
 - e. standard precautions will be utilized at all times;
 - f. in the event of a body fluid exposure to staff or another inmate, the source of the exposure must give consent to be tested;
 - g. patients with positive rapid test results will be scheduled for an appointment with a provider. Blood test confirmation will be drawn automatically; and
 - h. all inmates who test positive for HIV will be managed by the physicians at MSP, and all those following the current guidelines for standards of care. Complicated cases, and those co-infected with Hep C will be referred to an infectious disease consultant for treatment plan development and follow up as indicated. All inmates who test positive for HIV or Hep C will be enrolled chronic care.

B. Inmate Education/Counseling

1. Preventative education on HIV & Hep C is an ongoing process available when an inmate requests specific information, and will be part of every inmate patient’s regular medical care. Prevention counseling will be included in the HIV testing or screening process.
2. Prior to testing each inmate tested for HIV will be given the “Subject Information” pamphlet that is provided with the test kit.
3. Prior to testing, key points of the “Ora-Quick” Subject Information” pamphlet will be reviewed with the inmate and the inmate will be allowed to ask questions on the pamphlet regarding testing. This is conducted in a classroom presentation at the intake unit within 1-2 weeks after admission.

C. Communicating HIV & Hep C Test Results

1. Positive HIV & Hep C test results shall be communicated in a private setting with direct contact between the inmate patient and the medical provider, during which time a treatment plan will be initiated.
2. In addition, when a positive test result is obtained/confirmed, the inmate will be referred to the Chronic Care Nurse for intensive individualized education on all aspects of HIV & Hep C.
3. Inmates will be informed by written notice of the results of the negative HIV & Hep C test in a timely and confidential manner (as per HS E-12.0).
4. Reporting of all positive results will be in compliance with Montana State laws and regulations.

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D. Ora-Quick Test Control Logs

1. The temperature log is as follows:
 - a. the designated Correctional Health Services Technician (CHST) and/or nurse will keep a daily log/record of the refrigerator temperature in which the controls are stored. Controls are maintained in a refrigerator at 35°-46°F;
 - b. testing will be performed at operating temperature 59°-99°F; and
 - c. testing kits will be stored unopened at 35°-80°F.
2. The external control log is as follows:
 - a. external control records will include:
 - 1) the date and time of control testing;
 - 2) the lot number and expiration of the test kit;
 - 3) the lot number and expiration date of the controls;
 - 4) the control results; and
 - 5) corrective action taken if control results are unacceptable.
 - b. Control records will be kept in order in which they were completed so they can be easily compared with the test records.
3. *Montana State Prison OraQuick Test Results Log (attachment B)* Test result records will include:
 - a. the date and time of testing;
 - b. an identifier for the person being tested (AO number);
 - c. a test kit lot number and expiration date;
 - d. test result;
 - e. action taken if the result was invalid;
 - f. identification of the person who performed the test; and
 - g. whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid or blood), and the confirmatory test results when they are available.

E. Quality Improvement

1. Rapid HIV & Hep C testing and results process will be monitored through the CQI process.

IV. CLOSING

Questions concerning this operational procedure will be directed to the Health Services Manager.

V. ATTACHMENT

Training Checklist for OraQuick Rapid HIV Testing
 Montana State Prison OraQuick Test Results Log

attachment A
 attachment B

Training Checklist for OraQuick Rapid HIV & Hep C Testing

Employee: _____

Instructions: Fill in dates when the employee observes and performs each objective or procedural step, when applicable. The employee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the employee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	Date Observed	Date Performed	Employee's Initials & Date	Trainer's Initials & Date
Read OraQuick ADVANCED procedure at (<i>see https://orc.orasure.com</i>)				
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, workspace)				
Utilizes Standard precautions				
Practice test with negative, positive HIV-1, positive HIV-2, Hep C external controls				
Give person getting tested the "Subject Information" pamphlet				
Label test device components and appropriate paperwork				
Provide proper instruction and observe an oral fluid collection and insertion of test device into vial				
Collect fingerstick specimen, put loop into vial and mix correctly				
Insert test device into vial				
Time test, read result				
Dispose of lancet and/or other biohazardous waste materials appropriately				
Record results on in medical file and log sheet				
Record internal and external quality control (QC) results in QC logs				
Evaluate a new test kit lot number and record results in QC log				
Report test result to the person being tested (one negative and one preliminary positive)				
Refer person or collect specimen for confirmatory testing				
Send confirmatory test specimen to referral laboratory and document				
Receive referral laboratory results and record results				
Explain what to do in QC results show a problem				

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***Confirmatory Testing**

AO #	Date and Time Specimen Collected	Kit Lot #	Test Kit Exp. Date	Actual Test Incubation Time	Test Result: N=non-reactive R=reactive* I=invalid**	Initials	Date Result Given to Inmate	Date Specimen Sent to Lab	Date Result Received	Result	Date Result Given to Inmate

* Reactive requires confirmatory testing.

** Invalid requires Corrective Action. Refer to Page 2.

Reviewed by and date: _____ / /

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****Corrective Action**

Date	Action Taken	Initials

Reviewed by and date: _____ / /